

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA EX
REL. LAURA DILDINE,

PLAINTIFF,

v.

AARTI D. PANDYA, M.D., A/K/A
ARATI D. PANDYA, M.D., AND
AARTI D. PANDYA, M.D., P.C.,

DEFENDANT.

Civil Action No.

1:13-CV-3336-LMM

**UNITED STATES' BRIEF IN OPPOSITION TO DEFENDANTS' PARTIAL
MOTION TO DISMISS AND MOTION TO STRIKE**

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The United States of America, by Byung J. Pak, United States Attorney, and David A. O'Neal and Austin M. Hall, Assistant United States Attorneys for the Northern District of Georgia, submits this Brief in Opposition to Defendants' Partial Motion to Dismiss and Motion to Strike.

INTRODUCTION

Defendants' Motion to Dismiss characterizes the United States' Complaint in Intervention (the "Complaint") as a mere criticism of Dr. Pandya's medical judgment. The Complaint allegations are far more extensive and egregious than that. The Complaint alleges that Defendants submitted claims for Medicare reimbursement based upon false diagnoses. It alleges that Dr. Pandya performed surgical procedures on patients who had no vision problems or complaints. It alleges that Defendants submitted Medicare claims for tests that were of worthless value or never interpreted by Dr. Pandya. The Complaint alleges that Defendants upcoded claims to receive higher reimbursement despite failing to meet the appropriate criteria. And it alleges that Defendants submitted claims for diagnostic tests that were never performed.

In their Motion to Dismiss, Defendants ignore most of these allegations, choosing instead to address the entire Complaint with a single argument that clinical decisions are immune from False Claims Act ("FCA") liability absent some objective falsity. Defendants' argument fails for several reasons. First, most of the Complaint allegations have nothing to do with Dr. Pandya's clinical judgment, and Defendants concede those allegations are well pled by failing to address them. Second, where the Complaint alleges that Defendants submitted

claims for surgical procedures that were not reasonable and necessary, the United States relies upon objective evidence of falsity, not mere differences of medical opinion. Third, Defendants' entire legal argument, that Dr. Pandya is the sole and final arbiter of what is reasonable and necessary for purposes of Medicare payment, is without merit.

Defendants also attempt to argue that the Complaint fails to allege that Defendants acted "knowingly," despite conceding that scienter under the FCA need not be pled with particularity. Although they concede that scienter under the FCA does not require actual knowledge, Defendants improperly focus on the United States' supposed failure to allege actual knowledge. Despite Defendants' attempts at misdirection, however, the Complaint alleges significant and troubling allegations that demonstrate that Defendants acted "knowingly" under the FCA.

Finally, Defendants argue that the United States' payment by mistake and unjust enrichment claims fail to state a claim and that portions of the Complaint must be stricken. These arguments can be summarily rejected as set forth below.

ARGUMENT

I. Applicable Legal Standards

Defendants have generally recited the correct legal standard for pleading a valid FCA claim. A complaint need only contain "a short plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), which "state[s] a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The

complaint allegations must “be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Twombly*, 550 U.S. at 555. “In an action under the False Claims Act, Rule 8's pleading standard is supplemented but not supplanted by Federal Rule of Civil Procedure 9(b).” *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1051 (11th Cir. 2015). The Rule 9(b) standard “is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act.” *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009).

The Complaint alleges that Defendants violated two subsections of the FCA commonly referred to as the false claims provision (31 U.S.C. § 3729(a)(1)(A)) and the false statement provision (31 U.S.C. § 3729(a)(1)(B)). To state a claim under the false claims provision, the United States must plead facts that, taken as true, establish: “(1) a false or fraudulent claim, (2) which was presented, or caused to be presented, for payment or approval, (3) with the knowledge that the claim was false.” *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017). To state a claim under the false statement provision, the United States must plead facts to establish that (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim. *Id.*

Defendants argue that the United States has failed to state a claim because the Complaint does not allege two essential elements of an FCA claim: falsity and scienter. As shown below, these arguments are meritless.

II. The Complaint Alleges That Defendants Submitted False Claims Under the FCA

The FCA imposes civil liability where a defendant knowingly presents a “false or fraudulent claim” to the government. 31 U.S.C. § 3729(a)(1)(A); *see also id.* § 3729(a)(1)(B). A false claim can “take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation.” S. Rep. No. 99-345, at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. Congress intended the FCA to “reach all types of fraud, without qualification, that might result in financial loss to the Government.” *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). “The Supreme Court has further determined that the FCA and the term ‘any claim’ must be construed liberally to effect the FCA’s broad purpose of protecting the government treasury from fraudulent claims.” *United States v. Govereh*, No. 1:07-CR-131-JEC, 2010 WL 28565, at *2 (N.D. Ga. Jan. 5, 2010) (citing *Hubbard v. United States*, 514 U.S. 695, 703 n.5 (1995)). As discussed further below, “proof of an objective falsehood is not the only means of establishing an FCA Claim.” *United States v. Adams*, 4:18-CV-0191, 2019 WL 1449642, at *9 (N.D. Ga. Mar. 8, 2019) (Murphy, J.) (citation and internal quotation marks omitted). Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed. *United States ex rel. Walker v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005).

Defendants read the United States’ 90-page, 257-pagagraph Complaint as a mere disagreement with Dr. Pandya’s medical judgment, which they claim cannot give rise to FCA liability. (MTD at 5-12.) Not so. As set forth below,

Defendants' argument ignores large portions of the Complaint, which allege that Defendants submitted false claims unrelated to Dr. Pandya's medical judgment. Defendants' legal argument, moreover, is inconsistent with the FCA and relevant case law and would improperly immunize physicians who submit claims for medically unnecessary services.

A. The Complaint's Allegations of Falsity

The Complaint alleges with specificity that, between January 1, 2011 and December 31, 2016, Dr. Pandya submitted a large number of false claims for surgical procedures, diagnostic tests, and office visits.¹ Because Defendants ignore or mischaracterize significant portions of the Complaint, the false claims are summarized below.

1. Defendants Submitted False Claims for Cataract Procedures and YAG Laser Procedures

a. Defendants Submitted False Claims Surgical Procedures That Were Not Reasonable And Necessary

The federal government will not reimburse a Medicare claim unless the services at issue were "reasonable and necessary," 42 U.S.C. § 1395y(a)(1)(A), and a provider must expressly certify that he or she is seeking reimbursement for "medically necessary services." (Compl. ¶ 28.) Defendants, however, submitted

¹ Defendants acknowledge that the United States adequately pled that Defendants submitted false claims for office visits. (MTD at 1 n.1.) Those allegations, therefore, are not discussed in detail in this brief.

claims for surgical procedures that were not reasonable and necessary given Dr. Pandya's patients' signs and symptoms.

Specifically, Dr. Pandya performed cataract extraction surgeries on Medicare beneficiaries who had minimal or no vision complaints, whose measured visual acuity did not reflect vision problems, and without determining whether glasses might help her patients. (Compl. ¶¶ 46-47, 51-52.) Similarly, she performed YAG laser procedures on patients who presented with no documented posterior capsule opacification ("PCO") and who did not have vision problems. (Compl. ¶ 88.) Accordingly, those claims were false. As discussed in more detail below, Defendants' arguments that questions of medical necessity are immune from liability under the FCA are unfounded.

b. Defendants Submitted False Claims for Upcoded Complex Cataract Extraction Procedures.

The Complaint also alleges that Defendants engaged in an "upcoding" scheme where they routinely billed Medicare for higher-reimbursing complex cataract surgeries using CPT Code 66982, rather than the routine cataract extractions under CPT Code 66984 that she actually performed. (Compl. ¶¶ 72-80.) Upcoding, a common form of Medicare fraud, refers to the "practice of billing Medicare for services or equipment designated under a code that is more expensive than what a patient actually needed or was provided." *United States v. Marder*, 208 F. Supp. 3d 1296, at 1314 n.21 (S.D. Fla. 2016) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 501 F.3d 493, 498 n.2 (6th Cir. 2007) (internal quotation marks omitted)). Here, the upcoded complex cataract extraction

claims were false because Defendants falsely represented that the surgery required the use of instrumentation or techniques not typically used in a routine cataract procedure, as is required by CPT Code 66982. (Compl. ¶ 73.)

Defendants attempt to classify the United States' upcoding allegations as being based upon a medical necessity theory and argue that such claims are protected by Dr. Pandya's medical judgment. (MTD at 8-12.) Defendants are mistaken. The United States has not alleged that Dr. Pandya unnecessarily used the complex techniques and procedures contemplated by CPT Code 66982. Instead, the Complaint alleges that Dr. Pandya did not use complex techniques or procedures and falsely claimed that she did by billing CPT Code 66982. These upcoded claims, therefore, were false because they "were not rendered as claimed." *Walker*, 433 F.3d at 1356.²

2. Defendants Submitted False Claims for Glaucoma-Related Diagnostic Tests

The Complaint also alleges that Defendants submitted false claims for certain glaucoma-related diagnostic tests. (Compl. ¶¶ 99-176.) Claims for these tests were false for several different reasons, each of which independently gives rise to FCA liability.

² Notably, Defendants have not moved to dismiss other upcoding allegations in the Complaint related to Defendants' billing of office visits, acknowledging that such arguments "are not susceptible to a motion to dismiss." (MTD at 1 n.1; see also Compl. ¶¶ 194-200.)

a. Defendants Submitted False Claims for Diagnostic Tests Based Upon False Glaucoma Diagnoses

The Complaint alleges that Dr. Pandya made false glaucoma-related diagnoses in order to bill for a battery of medically unnecessary diagnostic tests. (Compl. ¶¶ 99-129.) Dr. Pandya rendered these diagnoses despite routinely failing to take intraocular pressure (“IOP”) measurements³ or observing any abnormalities with respect to the optic nerve indicative of glaucoma. (Compl. ¶¶ 115-117.) By falsely representing that the patients met the criteria for the glaucoma-related diagnoses, Defendants were able to bill Medicare for numerous diagnostic tests such as visual field tests (“VFT”), optical coherence tomography (“OCT”), and fundus photography, none of which would have been payable absent the glaucoma diagnoses. (Compl. ¶ 119.)

The claims for the diagnostic tests discussed above were false because they were based upon false diagnoses. *See Hill v. Morehouse Med. Assocs.*, No. 02-14429, 2003 WL 22019936, at *4-*5 (11th Cir. Aug. 15, 2003) (holding district court erred in dismissing complaint alleging defendants submitted false claims based upon use of false diagnosis codes); *Adams*, 2019 WL 1449642, at *9 (denying motion to dismiss and holding that government alleged Defendants submitted claims bearing false diagnoses); *United States v. Crumb*, No. 15-0655-WS-N, 2016 WL 4480690, at *11-14 (S.D. Ala. Aug. 24, 2016) (rejecting defendants’ argument that complaint was restricted to medical necessity theory where it alleged

³ Elevated IOP is the single-most important risk factor for glaucoma. (Compl. ¶ 114.) Where Dr. Pandya did record IOP measurements, those readings were frequently within normal limits. (Compl. ¶ 115.)

falsified diagnoses); *see also United States v. Rite Aid Corp.*, No. 2:12-cv-01699-KJM-
EFB, 2018 WL 4214887, at *3 (E.D. Cal. Sept. 5, 2018); *United States ex rel. Ramsey-
Ledesma v. Censeo Health, LLC*, No. 3:14-CV-00118-M, 2016 WL 5661644, at *5-7
(N.D. Tex. Sept. 30, 2016).⁴

Defendants' Motion to Dismiss fails to address the Complaint allegations regarding false glaucoma-related diagnoses.

**b. Defendants Submitted False Claims for Visual Field Tests That
Were Never Performed**

The Complaint also alleges that the Defendants submitted false claims for visual field tests ("VFTs") that were never performed. (Compl. ¶¶ 137-143.) In approximately April 2013, Defendants' VFT machine became inoperable. (Compl. ¶ 137.) Defendants, however, continued to bill for VFT tests that had not been completed. (Compl. ¶ 138.)

Claims for services not rendered are "paradigmatic" examples of factually false claims, which violate the FCA. *United States v. Spectrum, Inc.*, 47 F. Supp. 3d 81 (D.D.C. 2014) (quoting *United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010); *see also Walker*, 433 F.3d at 1356 ("Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed."); *Barker ex rel. United States v. Columbus Reg'l Healthcare Sys., Inc.*, 977 F. Supp. 2d 1341, 1344 (M.D. Ga. 2013)

⁴ Alternatively, such diagnostic tests were not reasonable and necessary because the patients did not have glaucoma-related conditions. 42 U.S.C. § 1395y(a)(1)(A).

(“False claims may include claims that sought payment for services that were not rendered or that were not medically necessary.”); S. Rep. No. 99-345, at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (“a false claim may take many forms, the most common being for goods or services not provided”).

Defendants fail to address these allegations that Defendants submitted false claims for services not rendered.

c. Defendants Submitted False Claims for Diagnostic Tests That Were of Worthless Value

The Complaint further alleges that Dr. Pandya billed Medicare for glaucoma-related tests that were of no diagnostic value. For example, Defendants routinely submitted claims for prematurely discontinued VFT tests, which produced reports bearing an error message stating that the test was “Not Completed or Was Interrupted.” (Compl. ¶¶ 145-146.) In similar fashion, Defendants submitted claims to Medicare for worthless OCT tests. (Compl. ¶¶ 157-166.) The Complaint also alleges that Defendants submitted false claims for fundus photographs that were completely unreadable. (Compl. ¶¶ 170-176.)

The Complaint, therefore, alleges that Defendants submitted false claims for worthless services. “A test known to be of no medical value, that is billed to the government would constitute a claim for worthless services, because the test is so deficient that for all practical purposes it is the equivalent of no performance at all.” *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (holding plaintiff adequately pled allegation that worthless diagnostic tests violated FCA) (citation and internal quotation marks omitted); *see also United States ex rel. Lee v.*

SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001) (If a party “knowingly or with deliberate ignorance charged the government for worthless services, then there would be fraud on the government that may be pursued under the FCA.”); *United States ex rel. Vainer v. Davita*, No. 1:07-CV-2509, 2012 WL 12832381, at *5 (N.D. Ga. Mar. 2, 2012) (holding Complaint pled falsity based upon worthless services theory); *cf. United States v. Houser*, 4:10-CR-012, 2011 WL 2007497, at *7-9 (N.D. Ga. Mar. 18, 2011) (applying FCA’s “worthless services” doctrine to criminal healthcare fraud statute).

Again, Defendants fail to address the Complaint’s worthless services allegations.

d. Defendants Submitted False Claims for Diagnostic Tests That Were Never Interpreted

The Complaint alleges that Defendants’ claims for diagnostic tests were also false because they were not interpreted by Dr. Pandya. (Compl. ¶¶ 130-176.) Certain of the diagnostic tests billed by Defendants – VFTs, OCTs, and fundus photos – require the physician to interpret the report in order for the claim to be payable by Medicare. (Compl. ¶¶ 148, 155-156, 169.) When Defendants submitted claims for these services, they falsely represented that Dr. Pandya interpreted these tests when she did not. Such claims, therefore, were false because they were “not rendered as claimed.” *Walker*, 433 F.3d at 1356. Defendants again fail to address this basis for falsity in their Motion to Dismiss.

B. Dr. Pandya's Medical Judgment Does Not Shield Defendants From Liability Under the FCA

Defendants summarize their argument that the Complaint fails to allege falsity as follows: "Whether the cataract procedures and glaucoma tests were medically necessary are issues of medical judgment and cannot be 'false' under the FCA as a matter of law." (MTD at 2.) In support of this argument, Defendants rely upon non-binding district court opinions adopting a minority view that a "mere difference of opinion between physicians, without more, is enough to show falsity" under the FCA." (MTD at 9 (quoting *United States v. AseraCare Inc.*, 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016)).

As set forth in detail above, however, the Complaint allegations are not based upon disagreements with Dr. Pandya's medical judgment. It was not a matter of medical judgment for Defendants to upcode cataract procedures. It was not a matter of medical judgment to bill Medicare for glaucoma testing for patients who did not have a valid glaucoma-related diagnosis. It was not a matter of medical judgment to bill Medicare for diagnostic tests that were never performed. It was not a matter of medical judgment to bill Medicare for worthless diagnostic tests. And it was not a matter of medical judgment to bill Medicare for diagnostic tests that were never interpreted as required by the relevant CPT Codes.

The only claims in the Complaint premised solely upon whether the services billed were reasonable and necessary are the allegations that Dr. Pandya billed for medically unnecessary cataract extractions and post-cataract YAG laser procedures. (Compl. ¶¶ 50-71, 81-98.) As such, Defendants' arguments that the

Complaint fails to allege falsity should be limited to these allegations. And in any event, Defendants' arguments are legally and factually deficient, as demonstrated below.

1. Medical Opinions Can Be False Under the FCA

Defendants rely primarily upon two non-binding district court decisions – *AseraCare*, 176 F. Supp. 3d 1282 and *United States v. Vista Hospice Care, Inc.*, No. 3:07-cv-00605-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016) – to contend that “differences in medical opinion alone cannot prove falsity without further proof of an objective falsehood.” (MTD at 9-10 (quoting *AseraCare*, 176 F. Supp. 3d at 1283).)⁵ Pursuant to this notion, a physician's medical decisions or opinions, no

⁵ In addition to *AseraCare* and *Vista Hospice*, Defendants also cite several cases for the proposition that “expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may disagree cannot be false.” (MTD at 9-10.) These decisions are either distinguishable or helpful to the United States. *See United States ex rel. Jones v. Brigham and Women's Hosp.*, 678 F.3d 72, 87-88 (1st Cir. 2012) (reversing district court's grant of summary judgment holding that data revisions were not purely a matter of scientific judgment); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (reversing dismissal and holding that complaint alleged FCA violations for medically unnecessary admissions and upgrade of transplant patients); *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 983 (10th Cir. 2005) (affirming dismissal of ERISA benefits allegations but cautioning that FCA claims could be based upon clinical medical judgments); *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13 (D.D.C. 2017) (holding complaint adequately alleged that defendant had submitted claims for medically unnecessary diagnostic tests).

matter how fanciful, unsupported or fringe, are immune from FCA liability.

That is not the law.

Congress intended the FCA to “reach all types of fraud, without qualification, that might result in financial loss to the Government.” *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). The FCA, therefore, applies to all “false or fraudulent” claims, 31 U.S.C. § 3729(a)(1)(A), (B); it does not suggest that only claims that are “objectively” false are actionable. The Supreme Court recently rejected a similar effort to narrow the FCA beyond its text, holding that the statute’s reference to “false or fraudulent claims” is not limited to claims that involve “misrepresentations about express conditions of payment.” *United Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016).

Indeed, Defendants’ argument that opinions cannot be fraudulent or false under the FCA has been repeatedly rejected by courts of appeals throughout the country.⁶ See *United States ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) (“It is possible for a medical judgment to be “false or fraudulent” as proscribed by the FCA”); *United States v. Paulus*, 894 F.3d 267, 275-76 (6th Cir. 2018) (“[O]pinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion.”); *United States ex rel. Loughren v. Unum Group*, 613 F.3d 300, 310 (1st Cir. 2010) (“An opinion may qualify as a false statement for

⁶ The *AseraCare* district court decision that forms the basis for Defendants’ argument is currently on appeal in the Eleventh Circuit. See *United States v. CGNSC Admin. Servs., LLC*, No. 16-13004 (11th Cir.) (argued Mar. 13, 2017).

purposes of the FCA where the speaker knows facts which would preclude such an opinion.”); *United States ex rel. Siewick v. Jamieson Sci. and Eng’g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000) (same); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999) (same).

In *Polukoff*, much like the allegations here, the complaint alleged that a cardiologist had performed thousands of medical unnecessary heart surgeries and submitted false claims to Medicare representing that those surgeries were medically necessary. *Polukoff*, 895 F.3d at 734. The Tenth Circuit, in reversing the district court’s dismissal, held that “[i]t is possible for a medical judgment to be ‘false or fraudulent’ as proscribed by the FCA.” *Id.* at 742. In so holding, the court recognized the “concern that a broad definition of ‘false or fraudulent’ might expose doctors to more liability under the FCA.” *Id.* at 743. The court held, however, that the Supreme Court has already addressed those concerns in *Escobar*: “Instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the [FCA]’s materiality and scienter requirements.” *Id.* (quoting *Escobar*, 136 S. Ct. at 2002).

Just as in *Polokoff*, the Complaint alleges that Dr. Pandya performed medically unnecessary procedures. And as the Tenth Circuit explained, “claims for medically unnecessary treatment are actionable under the FCA.” *Id.* (quoting *United States ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (internal quotation marks omitted)). The Eleventh Circuit similarly has recognized FCA violations for services that are not medically necessary. *See*

United States v. HPC Healthcare, Inc., 723 F. App'x 783, 788 (11th Cir. 2018) (“In the healthcare context, a False Claims Act violation typically involves billing for services not provided or not medically necessary.”).

A court within this District recently provided a roadmap that may be used to dispose of Defendants’ falsity arguments in this case. In *United States v. Adams*, the government alleged that the Dr. Adams performed chelation therapy, a service payable by Medicare to treat patients with heavy metal poisoning. 2019 WL 1449642, at *5. Dr. Adams, however, used these treatments for conditions such as circulation issues, autism, and premature aging, while falsely submitting claims with the diagnosis code for lead poisoning. *Id.* As here, the defendants moved to dismiss the government’s complaint, arguing that differences in clinical opinion cannot be false. *Id.* at *8. The court rejected that argument and “agree[d] with those courts that have concluded that a physician’s subjective medical opinions or judgments can be false for purposes of the FCA.” *Id.* at *9.⁷ The court further held that defendants’ “opinion argument” failed in light of the government’s allegations that the claims contained false diagnoses. *Id.* Defendants’ arguments here fail for the same reasons.

⁷ Other district courts across the country have similarly rejected Defendants’ arguments. See, e.g., *United States v. Robinson*, No. 13-cv-27-GFVT, 2015 WL 1479396, at *5 (E.D. Ky. Ma. 31, 2015 (“[P]roof of an objective falsehood is not the only means of establishing an FCA claim.”); *United States v. SavaSeniorCare, LLC*, No. 3:11-00821, 2016 WL 5395949, at *13 (M.D. Tenn. Sept. 27, 2016) (“[F]acts that rely upon clinical judgment are not . . . excluded from liability under the FCA.”) (internal citations omitted)).

2. Even Under the Standard Advocated by Defendants, the United States Has Alleged Falsity

Even under the erroneous legal theory advocated by Defendants, the Complaint adequately pleads falsity under the FCA. As discussed above, Defendants advocate that the Court adopt the holding of the district court in *AseraCare* that “differences in medical opinion ‘alone cannot prove falsity without further evidence of an objective falsehood.’” (MTD at 9-10 (quoting *AseraCare*, 176 F. Supp. 3d at 1283.)) The district court’s holding in *AseraCare*, however, is based on the unique certification process for hospice claims in which “hospice certifying physicians and medical experts look at the very same medical records and disagree about whether the medical records support hospice eligibility,” *i.e.*, how long the patient would live. *AseraCare*, 176 F. Supp. 3d at 1283.

Where, as here, Dr. Pandya’s clinical decisions are contradicted by objective facts, the rule set forth in *AseraCare* would be inapplicable. Indeed, *AseraCare* itself acknowledged this fact in public filings before the Eleventh Circuit:

In *Paulus*, the statement made by a physician involved the degree of stenosis (*i.e.*, blockage) in an artery, which the Sixth Circuit held is ‘a fact capable of proof or disproof.’ By contrast, this appeal involves a certifying physician’s prognosis of a hospice patient’s life expectancy, which necessarily and by law involves a subjective opinion.

United States v. GGNSC Admin. Servs., No. 16-13004, Response to Fed. R. App. P. 28(j) Letter (11th Cir.) (filed June 27, 2018).

This is not a hospice case. The Complaint makes no allegations that are based upon subjective opinion. Dr. Pandya's own medical records provide objective facts that establish that her patients did not need cataract surgery and did not have glaucoma. For example, the Complaint alleges that Dr. Pandya performed cataract surgeries on Patient A.1 despite the fact that she had no vision complaints, her vision without glasses was 20/20 in her right eye and 20/30 in her left eye. (Compl. ¶ 56-63.) As in *Paulus*, whether Patient A.1's cataracts had progressed to the point that cataract surgery was reasonable and necessary is "a fact that is capable of proof or disproof." *Paulus*, 894 F.3d at 275. The Complaint is replete with similar examples.

3. Defendants' Arguments Regarding Medical Necessity Are Improper at the Pleading Stage

Defendants' motion should also be denied because "determinations as to medical necessity or the reasonable interpretation of Medicare guidance are inappropriate at the motion to dismiss stage." *Adams*, 2019 WL 144642, at *9; see also *United States v. Snap Diagnostics, LLC*, No. 1:4-CV-3988, 2018 WL 2689270, at *3 (N.D. Ill. June 5, 2018) (holding "disagreements about medical necessity are inappropriate at this stage of litigation."); *United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F.Supp.3d 13, 28 (D.D.C. 2017).

C. The Complaint's Allegations Are Grounded in Violations of Legal Requirements, Not Guidance Documents

Defendants falsely claim that the United States "fails to identify any binding law or regulation that prohibits Dr. Pandya (or any ophthalmologist) from

submitting claims for the ophthalmologic services at issue in this case.” (MTD at 13.) They further argue that references in the Complaint to CMS National Coverage Determinations (“NCDs”) should be disregarded because they are not legally binding. (MTD at 15.) The upshot of Defendants’ argument is that absent a statute or regulation specifically defining the contours of when every possible service or procedure is medically necessary, physicians like Dr. Pandya can bill Medicare for whatever they please. Again, this is not the law.

Contrary to Defendants’ assertion, the United States does not rely upon agency guidance as a basis to plead that Dr. Pandya submitted false claims for unnecessary surgical procedures. The Complaint alleges that Dr. Pandya submitted false claims in violation of a statute, 42 U.S.C. § 1395y(A)(1)(A), because such services were not “reasonable and necessary.” (Compl. ¶¶ 21, 25-26.) The Complaint explains the basis for these allegations at length and provides specific examples of false claims. (Compl. ¶¶ 46-47, 50-71, 81-98.)

“Medicare claims may be false if they claim reimbursement for services or costs that . . . are not reimbursable” by the Department of Health and Human Services (“HHS”). *Walker*, 433 F.3d at 1356. The Secretary of HHS has broad discretion to determine whether services are reasonable and necessary, and therefore reimbursable, either “by promulgating a generally applicable rule or by allowing individual adjudication.” *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *see also Polukoff*, 895 F.3d at 735 (holding Medicare is entitled to “make individual claim determinations, even in the absence of [a national or local coverage determination], . . . based on the individual’s particular factual situation”). “One

factor that [Medicare] contractors consider when deciding whether a service is ‘appropriate’ is whether it is ‘[f]urnished in accordance with accepted standards of medical practice for diagnosis or treatment of the patient’s condition.’”

Polukoff, 895 F.3d at 736 (quoting Medicare Program Integrity Manual § 13.5.1).

The medical necessity requirement, therefore, applies even where the government has not issued guidance or promulgated a regulation defining the contours of medical necessity for a specific service or procedure. As the court in *Adams* recently explained, “Dr. [Pandya] cannot avoid those allegations simply by arguing, in [her] own view, the treatments [she] administered were medically necessary.” *Adams*, 2019 WL 144642, at *9; see also *United States ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *6 (E.D.N.Y. May 13, 2014) (“[if] physician determinations of reasonableness and necessity controlled claim payment, there would be no need for a claim reimbursement process at all.”).

As with any other type of litigation, the finder of fact can weigh the evidence and apply the appropriate standard of proof to determine whether a claim was reasonable and necessary. See *United States v. Joseph*, 703 F.3d 1082, 1097 (11th Cir. 2013) (affirming conviction of a physician for prescribing without legitimate medical purpose and holding that “it was for the jury to resolve the conflicting testimony and determine whether [defendant] had acted in accord with the accepted standard of medical practice.”); *United States v. Patel*, 485 F. App’x 702, 709 (5th Cir. 2012) (affirming healthcare fraud conviction of physician for performing unnecessary procedures and holding jury “was permitted to credit” the testimony of government experts over contrary evidence).

This is not to say that the potential for reasonable minds to disagree about whether a medical procedure was necessary is not relevant to FCA liability. Such evidence would be relevant, but not because it would preclude a finding of falsity. Instead, the potential for a reasonable but erroneous belief that a claim was eligible for payment would go to scienter: to “whether the defendant actually knew or should have known that its conduct violated a regulation.” *Phalp*, 857 F.3d at 1155; *see also Escobar*, 136 S. Ct. at 2002 (“[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act’s materiality and scienter requirements.” (citation and internal quotation marks omitted)).

Of course, where HHS does offer broadly applicable determinations regarding the payment of claims through NCDs, those determinations are binding on providers. “An NCD is a determination by the Secretary [of HHS] of whether a particular item or service is covered nationally under Medicare.” 42 C.F.R. § 405.1060(a)(1). “NCDs are considered substantive rules, which carry the force of law.” *Adams*, 2019 WL 1449642, at *10 (quoting *Advanced Diabetes Treatment Ctrs., LLC v. Sebelius*, No. 09-61698, 2011 WL 13268857, at *4 (S.D. Fla. Apr. 7, 2011) (internal quotation marks omitted)). “Defendants thus cannot avoid liability based on their argument that NCDs are non-binding.” *Id.*

As for the applicability of the NCDs cited in the Complaint, Defendants take issue because NCD 80.9 and 80.6 regarding VFTs and fundus photography respectively, state that such tests may be used for conditions other than

glaucoma. (MTD at 13-14.) Defendants miss the point. The Complaint alleges that Dr. Pandya's own medical records falsely state that the VFTs and fundus photos were being employed based upon false glaucoma-related diagnoses. (Compl. ¶¶ 108-129.) The fact that a VFT or fundus photograph might have some use for a condition not diagnosed or referenced by Dr. Pandya is irrelevant.

Finally, Defendants improperly attempt to invoke an internal Department of Justice memorandum, referred to by Defendants as the Brand Memo, to argue that guidance documents should not be used as the basis for liability in civil enforcement actions. (MTD at 15-16.) As an initial matter, the Brand Memo itself states that it "is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any manner civil or criminal."⁸ Moreover, the Department of Justice recently clarified the Brand Memo in revisions to the Justice Manual, which state that guidance documents are perfectly appropriate "to establish violations of the principal requirement that procedures billed to Medicare and Medicaid be medically 'reasonable and necessary.'"⁹ Defendants' reliance on the Brand Memo is, therefore, misplaced. *Adams*, 2019 WL 144642, at *11.

⁸ Memorandum from the Associate Attorney General, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018), *available at* <https://www.justice.gov/file/1028756/download>

⁹ Department of Justice, Justice Manual § 1-20.202 (Dec. 20, 2018), *available at* <https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation#1-20.202>

As set forth above, physicians like Dr. Pandya do not decide what the government will deem to be medically necessary for purposes of Medicare payment. The Complaint pleads more than sufficient information to establish that Dr. Pandya submitted claims for services that were not reasonable and necessary under 42 U.S.C. § 1395y(A)(1)(A).

III. The Complaint Sufficiently Alleges Scienter Under the FCA

The FCA imposes liability where the defendant “knowingly” submits false claims or uses false records or statements material to a false claim. 31 U.S.C. § 3729(a)(1)(A), (B). The FCA defines “knowing” and “knowingly” to encompass actual knowledge; deliberate ignorance of the truth or falsity of information; or reckless disregard of the truth or falsity of information. *Id.* § 3729(b)(1)(A). The FCA requires “no proof of specific intent to defraud.” *Id.* § 3729(b)(1)(B). At the pleading stage, “knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b); *see also United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1224 (11th Cir. 2012).

According to Defendants, the United States’ FCA claims should be dismissed because the “Complaint does not adequately alleges that Dr. Pandya acted with the requisite scienter.” (MTD at 16.) As shown below, Defendants are wrong.

A. Defendants Improperly Attempt to Limit the United States to an Actual Knowledge Requirement

Defendants concede that scienter under the FCA can be satisfied by showing either actual knowledge, deliberate ignorance, or reckless disregard. (MTD at 16.) In the next breath, however, Defendants attempt to limit the United States to

an actual knowledge standard, arguing that the United States has not pled sufficient facts to show actual knowledge. (MTD at 17.) This attempt to limit the United States to an actual knowledge standard is improper.

The Complaint alleges that Defendants submitted false claims “with ‘actual knowledge’ of, were ‘recklessly indifferent,’ or deliberately ignorant to the falsity associated with such claims.” (Compl. ¶ 222.) Because scienter may be alleged generally, this allegation alone is sufficient to plead a FCA claim. *See Matheny*, 671 F.3d at 1224; *Crumb*, 2016 WL 4480690, at *27 (holding the government need not “plead the factual basis which gives rise to a ‘strong inference’ of fraudulent intent”); *United States ex rel. Bibby v. Wells Fargo Bank, N.A.*, 906 F. Supp. 2d 1288, 1295 (N.D. Ga. 2012) (“In contrast to the particularized standard a complainant must use in alleging the mechanics of the fraud, a complainant may plead the scienter portion of the fraud generally.”).

B. The Complaint Contains Specific Allegations Regarding Defendants’ “Knowledge” Under the FCA

Although the Complaint need only allege scienter generally, it goes substantially further and identifies a host of facts that establish that Defendants acted “knowingly” under the FCA. The Complaint alleges that Dr. Pandya entered into a provider agreement with HHS-CMS in which she certified that she would only submit claims for services that were actually performed and medically necessary. (Compl. ¶¶ 33-34.)¹⁰ Despite these certifications,

¹⁰ Defendants dispute that such allegations can give rise to scienter under the FCA (MTD at 17-18), but courts disagree. *See United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) (holding

Defendants suddenly and dramatically increased Medicare billing after the retirement of Dr. Pandya's former employer, despite no material change in Dr. Pandya's patient population. (Compl. ¶¶ 37-40, 76-78, 85-87, 109-113, 132-133, 191-192, 211, 217.)

Defendants' claims were so inconsistent with other ophthalmologists that Dr. Pandya began receiving notices from multiple insurers, including Medicare, informing her that she was submitting claims significantly in excess of her peers. (Compl. ¶¶ 226-229.) Despite these notices, Defendants continued to submit false claims. Then, after federal agents executed a search warrant on Defendants' office in February 2014, the Complaint alleges that Defendants sharply decreased billing for many of the services at issue in this case, evidencing consciousness of guilt.¹¹ (Compl. ¶¶ 38, 40, 78, 86, 211, 224-225.) Defendants were so brazen, however, that they resumed submitting false claims the following year. (*Id.*)

The nature of the allegations against Dr. Pandya herself further forecloses the possibility that she simply made innocent mistakes. The Complaint alleges that

government alleged knowing violations of FCA where defendants certified on Medicare enrollment form that they would comply with a statute and failed to do so); *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253, 2013 WL 1289260, at *3 (S.D. Fla. Mar. 27, 2013) (same); cf. *United States v. Medina*, 485 F.3d 1291, 1301 (11th Cir. 2007) (affirming healthcare fraud conviction for claims submitted after certifications of compliance to Medicare).

¹¹ Defendants argue that that the impact of the search warrant on Dr. Pandya's billing has no bearing on Defendants' knowledge. (MTD at 18-19.) They are wrong. See *Patel*, 485 F. App'x at 709 ("In addition, there was evidence that Patel abruptly changed course, evincing possible consciousness of guilt, after the government executed its search warrant.").

Dr. Pandya performed cataract surgeries and YAG procedures and billed them to Medicare despite the fact that patients experienced little to no vision problems and despite the fact that she took no steps to determine whether glasses would help the patients. (Compl. ¶¶ 51, 56, 59-60, 64-65, 88, 90-91, 94). Similarly, the Complaint alleges that Dr. Pandya diagnosed as many as 95% of her Medicare patients with a glaucoma-related diagnosis, which is nearly 10 times the prevalence rate for glaucoma in Georgia. (Compl. ¶¶ 108-110.) And, Dr. Pandya submitted claims for diagnostic tests that were plainly unreadable, contained error messages, or were otherwise invalid. (Compl. ¶¶ 146-147, 159-160, 172-173.) Generously construed, such conduct establishes that Dr. Pandya was, at the bare minimum, deliberately ignorant of the falsity of her claims or recklessly disregarded whether such claims were false.

The Complaint also alleges more sinister conduct that easily meets the standard for knowledge under the FCA. Dr. Pandya instructed her staff to discontinue VFT tests prior to their being completed. (Compl. ¶¶ 145-146.) When the VFT machine broke in 2013, Defendants continued to submit tests for VFTs that were never conducted and placed an asterisk in the patient's medical record to denote this fact. (Compl. ¶¶ 137-143.) And because VFT tests were being used for false Medicare billing rather than legitimate medical care, Dr. Pandya negotiated a reduction in the purchase price for a new VFT machine by foregoing any training for her staff. (Compl. ¶ 150.)

The Complaint further alleges that Dr. Pandya prefilled superbills and changed Medicare coding completed by another provider who filled in for Dr.

Pandya while she was on vacation. (Compl. ¶¶ 196-200.) And finally, as further evidence of Defendants' overall fraudulent practices, Defendants submitted fraudulent names to Bausch + Lomb to obtain eye kits that the company provided free to patients, so that Defendants could charge their patients for these kits. (Compl. ¶¶ 230-234.) Accordingly, for the reasons set forth above, Defendants' contention that the Complaint fails to allege scienter under the FCA is without merit. *See Matheny*, 671 F.3d at 1224.

IV. The Complaint Adequately Pleads Claims for Payment by Mistake of Fact and Unjust Enrichment

Defendants argue that the United States' claims for payment by mistake of fact (Count III) and unjust enrichment (Count IV) must be dismissed. (MTD at 21-25.) Defendants first contend that these claims should be dismissed because the United States fails to state whether its claims arise under federal common law or Georgia state law. (MTD at 21.) This argument is without merit. *See Adams*, 2019 WL 1449642, at *13 (rejecting identical argument and applying federal law); *United States ex rel. Heesch v. Diagnostic Phys. Group, P.C.*, No. 11-0364, 2014 WL 2155363, at *10 (S.D. Ala. May 22, 2014) (rejecting same argument and holding that "rights arising under a nationwide federal program such as Medicare are governed by federal law, not state law.").¹²

¹² Defendants are not helped by *United States ex rel. St. Joseph's Hosp. Inc. v. United Dist., Inc.*, 918 F. Supp. 2d 1306, 1316 (S.D. Ga. 2013), which simply granted the Government leave to replead in order to specify whether it was pursuing federal or state law claims.

The “payment by mistake” doctrine enables the United States to recover payments made under a material and erroneous belief that the payments were properly owed. *See United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 776 (N.D. Tex. 2003). Similarly, under the doctrine of unjust enrichment, “a person is unjustly enriched if the retention of a benefit would be unjust[,]” and the United States can recover where: (1) it has a reasonable expectation of repayment, (2) the recipient of the payment should expect to repay, and (3) society’s expectations would be defeated by non-payment. *United States v. Rogan*, 459 F. Supp. 2d 692, 728 (N.D. Ill. 2006).

The United States has pled *prima facie* claims for recovery under both doctrines. The Complaint alleges that Medicare paid claims to Defendants based upon the mistaken and material belief that the billed service were reasonable and necessary, were based upon valid diagnoses, and/or were provided as claimed. Such facts give rise to the alternate causes of action of payment by mistake of fact and unjust enrichment. *Adams*, 2019 WL 1449642, at *12-*13.

V. Defendants’ Motion to Strike is Without Merit

Defendants move pursuant to Federal Rule of Civil Procedure 12(f) to strike Paragraphs 230-235 of the Complaint, which discuss Defendants’ scheme to obtain Bausch + Lomb surgery bags using fake names, arguing that such allegations are irrelevant to the claims at issue. (MTD at 25-29.) Pursuant to Rule 12(f), “the court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). “However, ‘it is axiomatic that motions to strike are not favored and are,

therefore, infrequently granted.’’ *Intelligent Payments, LLC v. 123 IT Support, Inc.*, 1:14-CV-2634-LMM, 2018 WL 3698978, at *1 (N.D. Ga. Jan. 23, 2018). As this Court has held, “[m]atter will not be stricken from a pleading unless it is clear that it can have no possible bearing upon the subject matter of the litigation. If there is any doubt as to whether under any contingency the matter may raise an issue, the motion should be denied.” *Id.* (citations and internal quotation marks omitted).

According to Defendants, because the Bausch + Lomb allegations do not affect government payment, they must be stricken. (MTD at 26.) As the Complaint makes clear, however, the fraudulent conduct alleged in Paragraphs 230-235 is highly relevant to “demonstrate[] her overall pattern and practice of maximizing revenue through deception.” (Compl. ¶ 230.) Indeed, these allegations are contained in Section IV of the Complaint which contains allegations relevant to whether Defendants submitted false claims “knowingly,” as defined by the FCA. *See* Fed. R. Evid. 404(b). To the extent that Defendants have evidentiary objections to the admissibility of Defendants’ Bausch + Lomb fraud scheme, they are free to file motions *in limine* prior to trial. *Kemper v. Equity Ins. Co.*, No. 1:15-cv-2961, 2016 WL 7428801, at *2 (N.D. Ga. Feb. 26, 2016) (denying motion to strike and holding that defendant could submit a motion *in limine* at the appropriate time to exclude evidence it believed to be unduly prejudicial); *Jordan v. Comcast Cable Commc’ns Mgmt., LLC*, No. 1:14-cv-03622-WSD, 2015 WL 4164826, at *2-*3 (N.D. Ga. Jul. 9, 2015).

CONCLUSION

For the reasons set forth herein, the United States respectfully request that Defendants' Partial Motion to Dismiss and Motion to Strike be denied.

Respectfully submitted this 26th day of April, 2019.

Respectfully submitted,

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Certificate of Compliance

I hereby certify, pursuant to Local Rules 5.1 and 7.1D, that the foregoing brief has been prepared using Book Antiqua, 13 point font.

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Certificate of Service

The United States Attorney's Office served this document today by filing it using the Court's CM/ECF system, which automatically notifies the parties and counsel of record, and by handing a copy to defense counsel:

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April 26, 2019

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